Filtration unit comprising two distinct filtering media and system of bags comprising it.

This invention relates to a filtration unit 1 for a biological fluid, in particular blood or blood components, of a type comprising an outer sheath 2 equipped with at least one inlet 3 to receive the fluid to be filtered and at least two outlets 4, 5 to collect the filtrate, the aforementioned unit 1 comprising two distinct filtering media 6, 7 that are arranged in the outer sheath 2 so as to form, between the two filtering media 6, 7, an inlet compartment 8 communicating with the inlet 3 and, on both sides of the filtering media 6, 7, an outlet compartment 9, 10 respectively in communication with an outlet 4, 5.

The invention also relates to a system of bags comprising such a unit 1, with the aforementioned system designed for the sterile closed-circuit filtration of the fluid.

The invention relates to a filtration unit for a biological fluid as well as a system of bags comprising such a unit, the aforementioned system being designed for the sterile closed circuit filtration of the fluid.

It typically applies to the filtration of blood or blood components as well as the separation and collection of the different components of the blood filtered in a set of satellite bags of the system of bags.

Such filtration units make it possible to eliminate a compound or a substance from the fluid, for example, eliminate the leukocytes or a viruscidal substance that was previously added.

Filtration units are already known that comprise an outer sheath containing a filtering medium able to retain leukocytes.

In such units, illustrated for example by document EP-A-0 526 678, it is classic to use a juxtaposition of filtering layers formed by a porous non-woven substance.

In fact, in this type of so-called deep filtration, the ability of the filtering media to retain the leukocytes is mainly a function of the quantity of matter crossed by the fluid, and therefore the thickness of the filtering media.

To improve the efficacy of this type of filtration, that is, to increase the quantity of leukocytes retained by the filtering media, an attempt was made to increase the thickness of the filtering medium, either by increasing the number of layers or by increasing their thickness.

However, this solution has a certain number of disadvantages.

In particular, the increase in the thickness of the filtering medium provokes a considerable reduction in the flow of the fluid passing through the filtering medium by gravity, and thereby increases the filtration time.

Moreover, the applicant noted that, as of a certain value, the increase in the thickness of the filtering medium no longer has a positive effect on the quantity of leukocytes retained by the filtering medium.

The invention thereby aims at correcting these disadvantages by in particular providing a unit having an improved filtration capacity, with the aforementioned unit integrated in a closed circuit system of bags to provide, in a simple manner, the separation and collection of the different components in the filtered blood.

For this purpose, and according to a first aspect, the invention provides a filtration unit for a biological fluid, in particular blood or blood components, of the type comprising an outer sheath equipped with at least one inlet to receive the fluid for filtration and at least two outlets to collect the filtrate, the aforementioned unit comprising two distinct filtering media that are arranged in the outer sheath so as to form, between the filtering media, an inlet compartment in communication with the inlet and, on both sides of the filtering media, an outlet compartment respectively in communication with an outlet.

According to a second aspect, the invention provides a system of bags for the sterile and closed-circuit filtration of a biological fluid, comprising a primary bag intended to contain the fluid for filtration, the aforementioned primary bag connected by means of a first tube and at one of its outlets to the inlet of a filtration unit described above, and a secondary bag intended to receive the filtrate, the aforementioned secondary bag connected by means of a second tube and at one of its inlets to the outlets of the aforementioned filtration unit.

Other goals and advantages of the invention will appear during the following description with reference to the appended drawings.

Figure 1 shows a side view and longitudinal section, of a filtration unit according to one embodiment of the invention.

Figure 2 shows a front view of the filtration unit in figure 1.

Figure 3 shows a front view diagram of a system of bags for the sterile, closed-circuit filtration of an erythrocyte concentrate, with the aforementioned system comprising:

- a primary bag intended to contain the fluid to be filtered, the aforementioned primary bag being connected by means of a first tube and at one of its outlets to the inlet of a filtration unit according to the invention;

- a secondary bag intended to receive the filtrate, the aforementioned secondary bag being connected by means of a second tube and at one of its inlets to the outlets of the aforementioned filtration unit;

- means for the collection of whole blood connected to an inlet from the primary bag; and

- a set of satellite bags connected to an outlet from the primary bag by means of a third tube, so as to be able to obtain, after the collection of the whole blood in the primary bag and centrifugation of the aforementioned primary bag, the filtration of the erythrocyte concentrate on the one hand and the collection of the platelet-rich plasma on the other hand in the set of satellite bags.

Figure 4 shows, in a front view diagram, a system of bags for the sterile closed-circuit filtration of the whole blood, the aforementioned system comprising:

- a primary bag intended to contain the fluid to be filtered, the aforementioned primary bag being connected by means of a first tube and at one of its outlets to the inlet of a filtration unit according to the invention;

- a secondary bag intended to receive the filtrate, the aforementioned secondary bag being connected by means of a second tube and at one of its inlets to the outlets of the aforementioned filtration unit;

- means for the collection of whole blood connected to an inlet from the primary bag; and

- a set of satellite bags connected to an outlet from the secondary bag by means of a third tube, so as to be able to obtain, after the collection of the whole blood in the primary bag, the filtration of the total blood as well as the collection, after centrifugation of the secondary bag, of the different components of the blood in the set of satellite bags.

Figures 1 and 2 show a filtration unit 1 of a biological fluid able to retain, by filtration, particles present in the aforementioned fluid.

In a specific example, the fluid is blood where blood components are formed and the unit 1 is able to retain, by filtration, the leukocytes and/or a viruscidal substance such as methylene blue or one of its derivatives.

In fact, the biological fluid is known to be subject to viral inactivation by means of a viruscidal substance that

was added to the fluid and, after this treatment, to eliminate the aforementioned viruscidal substance by filtration.

Moreover, and possibly simultaneously, it is desirable to eliminate the leukocytes from the blood of blood components before their transfusion.

In the embodiment shown represented in figures 1 and 2, the unit 1 comprises an outer sheath 2 equipped with an inlet 3 to receive the fluid to be filtered and two outlets 4, 5 to collect the filtrate.

The unit 1 also comprises two distinct filtering media 6, 7 that are arranged in the outer sheath 2 so as to form, between the filtering media 6, 7, an inlet compartment 8 communicating with the inlet 3 and, on both sides of the filtering media 6, 7, an outlet compartment 9, 10 respectively communicating with an outlet 4, 5.

In the description, the terms "inlet", "outlet", "upstream" and "downstream" are defined with respect to the direction of the circulation of the fluid in the filtration unit 1 refer to the arrows in figures 1 and 2.

When the filtration unit 1 is supplied by means of an inlet 3, the aforementioned fluid fills the inlet compartment 8 and then simultaneously and obviously goes through the two filtering media 6, 7 to be collected in the two outlet compartments 9, 10. The filtrate can then be collected through the two outlets 4, 5.

The filtration unit 1 in particular has the advantage of enabling the parallel filtration of the fluid through the two distinct filtering media 6, 7, leading to an optimisation of the ratio between the volume of the unit 1

and the quantity of fluid that can be filtered without the risk of clogging.

This advantage in particular provides a more compact unit 1 than if the two filtering media 6, 7 are present in two distinct sheaths, making it better adapted for possible subsequent centrifugation.

In addition, by increasing the filtration surface, the unit 1 enables both faster and better quality filtration, while reducing the probability of clogging.

According to one embodiment, the two filtering media 6, 7 are identical and formed by one or several layers of a porous material in the forms of a non-woven and/or porous membrane, for example a hydrophilic material such as cellulose or its derivatives, for example cellulose acetate, or such as a polymer or a co-polymer made of polypropylene, polyester, polyamide, high or low density polyethylene, polyurethane, polyvinylidene fluoride and their derivatives.

These polymer products are not generally naturally hydrophilic and must be processed by physical and/or chemical methods to have the aforementioned hydrophilic properties.

These treatments, for example, consist in the grafting of hydrophilic substitutes, for example, hydroxyl or carboxyl groups, on the polymer, according to known methods.

Such polymers made hydrophilic by physical and/or chemical processing are available on the market.

The number of layers as well as their porosity and/or composition, that may be identical or different according to the layer, are adapted according to the fluid to process and/or the substance to be eliminated.

Moreover, a pre-filter and/or post-filter, for example formed from a porous membrane and/or one or several specific non-woven layers, may be deposited against the filtering medium 6, 7, upstream and downstream from it respectively, so as to improve the filtration of the fluid.

An embodiment of a filtration unit 1 is described below, in relation to figures 1 and 2.

In the embodiment shown, the outer sheath 2 is flexible and formed by the assembly of two sheets 11, 12 made of flexible plastic, mutually assembled for example by welding, on their periphery.

Filtering media 6, 7 are maintained in the outer sheath 2 respectively by impervious deformable means of association that are formed by a flexible frame 13a, 13b.

The flexible frames 13a, 13b are formed by an assembly of two, for example plasticised sheets, between which the filtering medium 6, 7 is placed.

The central part of these two sheets is perforated and each contains at least one opening 14 for the passage of the biological fluid to filter.

The two sheets are appended, preferably at the periphery of the filtering medium 6, 7, for example by a welding run 15 made through the filtering medium 6, 7, providing both the fixation of the filtering medium 6, 7 as well as the impermeability.

The welding of the sheets through the filtering medium 6, 7 provokes a compression, forming an impervious weld around the filtering medium 6, 7.

The periphery of the flexible frames 13a, 13b are welded with the outer sheets 11, 12 forming the outer sheath 2, mutually along their entire circumference, thereby providing the impermeability.

During this welding, the inlet 3 formed by a portion of tube, is placed between the two flexible frames 13a, 13b and the outlets 4, 5 formed by a portion of tube respectively, are placed on both sides of the flexible frames 13a, 13b.

Thereby, the inlet compartment 8 formed between the two filtering media 6, 7 communicates with the inlet 3 and each outlet compartment 9, 10 formed between a sheet 11, 12 respectively and a filtering medium 6, 7 communicates with an outlet 4, 5.

This association with flexible frames 13a, 13b has the advantage of forming an inlet compartment 8 with a small initial volume that increases with the supply in fluid by deformation of the flexible frames 13a, 13b under the effect of the pressure exerted by the fluid.

Therefore, upon completion of filtration, the return of the flexible frames 13a, 13b to the initial position provokes, by a reduction in the volume of the inlet compartment 8, an acceleration in the filtration that improves the total time of filtration while limiting the lost volume of the filtration unit 1.

To prevent the filtering medium 6, 7 from sticking to the outer sheath 2, and thereby hindering the flow of the biological fluid, two spread rods 16, 17 are placed inside each outlet compartment 9, 10 between the filtering medium 6, 7 and the outer sheath 2.

These two rods 16, 17 clear the outlet compartments 9, 10 from the filtering medium 6, 7 and thereby prevent the

filtering medium 6, 7 from caking against the inner wall of the outer sheet 11, 12.

Rods 16, 17 can be made from flexible tubes welded, for example, at the inner wall of the sheet of the outer sheath 2, for example, at the peripheral weld.

It is evident that the number of spread rods 16, 17 may vary, for example, according to the dimensions of the filtration unit 1.

For example, it is possible to anticipate a single spread rod folded so as to form a loop inside the outlet compartments 9, 10.

Preferably, flexible rods 16, 17 are used, so as not to hinder the folding possibilities of the filtration unit 1.

In another embodiment (not shown), the outer sheath 2 is rigid, for example made of a rigid plastic such as polycarbonate.

Now, in relation to figures 3 and 4, a first and second embodiment of a system of bags for the sterile and closed-circuit filtration of a biological fluid is described, with the aforementioned system comprising a filtration unit 1 as described above.

For this purpose, the systems with bags comprise a primary bag 18 intended to contain the fluid to be filtered, the aforementioned primary bag 18 is connected by means of a first tube 19 and at one of its outlets 20 to the inlet 3 of the filtration unit 1 and a secondary bag 21 intended to receive the filtrate, the aforementioned secondary bag is connected by means of a second tube 22 and at one of its inlets 23 to the outlets 4, 5 of the aforementioned filtration unit 1.

In particular, a single tube 22 can be connected, for example by means of a Y-connection 24, to two portions of tube associated with an outlet 4, 5 respectively.

In the first embodiment (figure 3), the system of bags also comprises means of collecting 25 whole blood connected to an inlet 26 from the primary bag 18 and a set of satellite bags 27, 28 connected to an outlet 29 from the primary bag 18 by means of a third tube 30.

After sterilisation, this system allows for the creation of a closed circuit comprising a succession of the following steps:

- collection of the whole blood in the primary bag 18;
- centrifugation of the aforementioned primary bag 18;
- filtration of the erythrocyte concentrate;
- collection of the platelet-rich plasma in the set of satellite bags 27, 28.

In the second embodiment (figure 4), the system of bags also comprises means of collecting 25 whole blood connected to an inlet 26 from the primary bag 18 and a set of satellite bags 27, 28 connected to an outlet 31 from the secondary bag 21 by means of a third tube 32.

After sterilisation, this system allows for the creation of a closed circuit providing a succession of the following steps:

- collection of the whole blood in the primary bag 18;
- filtration of the whole blood;
- centrifugation of the secondary bag 21;

- collection of the different components of the blood in the set of satellite bags 27, 28.

In a variant, tubes 19, 22, 30, 32 are flexible, can be scored and welded in order to be able, after filtration and before centrifugation, to separate the filtration unit 1 from the system of bags.

CLAIMS

1. A filtration unit (1) for a biological fluid, in particular blood or blood components, of a type comprising an outer sheath (2) equipped with at least one inlet (3) to receive the fluid to be filtered and at least two outlets (4, 5) to collect the filtrate, the aforementioned unit (1) is characterised in that two distinct filtering media (6, 7) are placed in the outer sheath (2) so as to form, between the filtering media (6, 7), an inlet compartment (8) communicating with the outlet (3) and, on both sides of the filtering media (6, 7), an outlet compartment (9, 10) respectively communicating with an outlet (4, 5).

2. A filtration unit according to claim 1, characterised in that the filtering media (6, 7) are formed from one or several layers of a porous material in the form of a non-woven and/or porous membrane, for example, a hydrophilic material such as cellulose or its derivatives, for example, cellulose acetate, or a polymer or a co-polymer made of polypropylene, polyester, polyamide, high or low density polyethylene, polyurethane, polyvinylidene fluoride and their derivatives, made hydrophilic by a physical or chemical process.

3. A filtration unit according to claim 2, characterised in that the different layers forming a filtering medium (6, 7) are of different porosity and/or composition.

4. A filtration unit according to any of claims 1 to 3, characterised in that the filtering media (6, 7) are maintained in the outer sheath (2) by means of

deformable, in particular flexible, impervious associations.

5. A filtration unit according to any of claims 1 to 4, characterised in that the outer sheath (2) is flexible, for example formed by two sheets of flexible plastic (11, 12) assembled along their periphery.

6. Filtration unit according to claims 4 and 5, characterised in that the means of association comprise a flexible frame (13a, 13b) in which the filtering medium (6, 7) is maintained, the flexible frame (13a, 13b) is formed by two flexible perforated sheets between which the filtering medium (6, 7) is placed, the aforementioned sheets are fixed on both sides at the periphery of the filtering medium (6, 7) by a weld run (15) made through the filtering medium (6, 7) and, on the other hand, at the periphery of the outer sheath (2) by welding with the sheets (11, 12) forming the outer sheath (2).

7. A system of bags for the sterile and closed-circuit filtration of a biological fluid, characterised in that it comprises a primary bag (18) intended to contain the fluid to be filtered, the aforementioned primary bag (18) is connected by means of a first tube (19) and at one of its outlets (20) to the inlet (3) of a filtration unit (1) according to any of claims 1 to 6, and a secondary bag (21) intended to receive the filtrate, the aforementioned secondary bag (21) is connected by means of a second tube (22) and at one of its inlets (23) to the outlets (4, 5) from the aforementioned filtration unit (1).

8. A system of bags according to claim 7, characterised in that it also comprises means for the collection (25) of whole blood connected to an inlet (26) from the primary bag (18) and a set of satellite bags (27, 28) connected to an outlet (29) from the primary bag (18) by means of a third tube (30) so as to be able to achieve, after the collection of the whole blood in the primary bag (18) and centrifugation of the aforementioned primary bag (18), the filtration of the erythrocyte concentrate on the one hand and the collection of the platelet-rich plasma on the other hand in the set of satellite bags (27, 28).

9. A system of bags according to claim 7, characterised in that it also comprises means for the collection (25) of whole blood connected to an inlet (26) from the primary bag (18) and a set of satellite bags (27, 28) connected to an outlet (31) from the secondary bag (21) by means of a third tube (30), so as to be able to achieve, after the collection of the whole blood in the primary bag (18), the filtration of the whole blood as well as the collection, after centrifugation of the secondary bag (21), of the different components in the blood in the set of satellite bags (27, 28).